October 14, 2002

The Honorable Lester M. Crawford, Jr.
Deputy Commissioner of Food and Drugs
Dockets Management Branch
Office of Management and Operations
Food and Drug Administration
United States Department of Health and Human Services
Room I-21
12420 Parklawn Drive
Rockville, Maryland 20857

Re: *Alex Cain, et al. v. Merck & Co., Inc. et al.,*
Docket No. CV-01-3411(SJ)
United States District Court
Eastern District of New York

Dear Commissioner Crawford:

We represent the plaintiffs in the above-captioned lawsuit pending in federal court in New York. Plaintiffs are suing on their own behalf and on behalf of a proposed class of all persons in the United States who have taken the prescription pain relievers rofecoxib and celecoxib, which are respectively marketed under the brand names Vioxx and Celebrex. We write to notify you that the Court has referred for determination by the Food and Drug Administration ("FDA") certain claims by the plaintiffs for injunctive relief and to request that you make such determination.

The background of this action is as follows:

On May 29, 2001, the plaintiffs filed a complaint against Merck & Co., Inc., the manufacturer and marketer of Vioxx; and against Pharmacia Corporation, Pfizer, Inc., and G.D. Searle & Co., the manufacturers and marketers of Celebrex, seeking, inter alia, medical monitoring, compensatory damages, and revised warnings and notice to class members. As the FDA is aware, a number of studies have shown, among other things, that taking and/or switching to selective cox-2 inhibitors such as Vioxx and Celebrex increases the propensity of the blood to clot, potentially leading to severe cardiovascular problems such as hypertension, stroke and myocardial infarction. On August 21, 2002, the Court, in ruling on a motion to dismiss filed by defendants, issued an order staying

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plaintiffs' claims to the extent that they seek notice and revised warnings, and directing plaintiffs to submit their request for such equitable relief to the FDA for review.

Specifically, the Court has stayed, pending the FDA's review, the questions of: (i) whether, based on recent and ongoing studies, the defendants should be ordered to locate and notify persons who have taken Vioxx and Celebrex of the serious health dangers and risks to which they have been and will continue to be exposed by taking and/or switching to these drugs; and (ii) whether the defendants should be ordered to provide revised and updated warnings in their advertising of these drugs and on drug labels and drug packaging.

Pursuant to 21 C.F.R. §§ 10.25 (c) and 10.60 (b), we respectfully request that FDA determine whether it shall agree to accept referral of this matter and institute a proceeding to consider whether it shall take administrative action to order the defendants to provide notice to class members and/or to order the defendants to revise the warnings for Vioxx and Celebrex.

For your convenience, we have enclosed copies of the Court's August 21, 2002 order and a copy of the Plaintiffs' Second Amended Complaint.[1]

Respectfully yours,

David A. Barrett

Enclosures

cc: The Honorable Sterling Johnson, Jr. (w/o Enclosures)
Theodore V.H. Mayer, Esq., counsel for defendant Merck & Co., Inc. (w/o Enclosures)
Steven Glickstein, Esq., counsel for defendant Pfizer Inc. (w/o Enclosures)
James D. Arden, Esq., counsel for defendants Pharmacia Corp. & G.O. Searle & Co. (w/o Enclosures)

[1] While the Court's August 21 Order by its terms applies to the plaintiffs' First Amended Complaint, the parties have stipulated that the Order is equally applicable to plaintiffs' subsequently-filed Second Amended Complaint.